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Lisa Treverrow

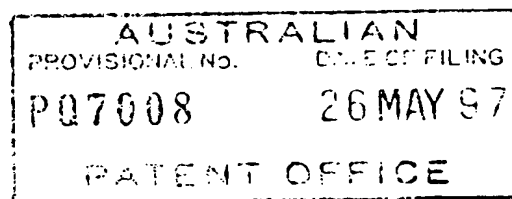
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ORIGINAL



**PROVISIONAL SPECIFICATION FOR AN INVENTION
ENTITLED**

Invention Title: **A METHOD AND MEANS OF DEPLOYING A
GRAFT**

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The invention is described in the following statement :

This invention relates to a method and means for introducing a self expanding graft which may be straight, tubular or bifurcated in form and intended for the endovascular repair of diseased or damaged vessels.

5 Throughout this specification the terms proximal and proximally are used for a position or direction towards the patients heart and the terms distal and distally are used for a position or direction away the patients heart.

10 In one form although this may not be the only or broadest form the invention may be said to reside in an introducer adapted for the introduction of a self expanding endovascular graft into a lumen of a patient, the graft having a proximal end and a distal end, the introducer comprising, a proximal attachment device adapted to be attached to the proximal end of the graft, a distal attachment device adapted to be attached to the distal end of the graft, each of the proximal and distal attachment devices attaching to the graft in such a manner that the graft can be held in tension therebetween and that
15 each end of the graft can individually be moved in proximal and distal directions and be rotated, and proximal releasing means associated with the proximal attachment device and distal releasing means associated with the distal attachment device to enable selective releasing of the proximal and distal ends of the graft.

20 In a preferred form of the invention the proximal attachment means has a long flexible extension on its proximal end to facilitate insertion of the introducer into a body lumen and its advancement along the lumen.

25 The proximal attachment device may be mounted on a flexible thin walled tube which extends in a distal diversion for the proximal attachment device to an external manipulation section of the introducer which is adapted to remain external of the patient.

The thin wall metal tube may include fluid connection means external of the patient to enable the introduction of a medical reagent therethrough.

30 The long flexible extension may include a hollow tube therethrough in fluid communication with the thin wall metal tube and a plurality of side holes to enable dispersion of the medical reagent proximal of the graft.

In a preferred form of the invention the distal attachment device is mounted on a flexible thick walled tubing and coaxial on the thin walled tube and extending in a distal direction to the external manipulation section and mounted such that the respective tubes can be moved together or
 5 independently.

There may be further included a haemostatic seal between the thin walled tube and the thick walled tube in the manipulation section.

There may be further included means to introduce a medical reagent into an annular space defined between the thin walled tube and the thick walled tube.

1 0 In a preferred form of the invention there may be a proximal trigger wire extending from the proximally attachment device to the manipulation section, the proximal trigger wire being adapted to activate the proximal releasing means and a distal trigger wire extending from the distal attachment device to the manipulation section, the distal trigger wire being adapted to activate the
 1 5 distal releasing means.

In a preferred form of the invention there may be included an external release mechanism for each of the proximal trigger wire and distal trigger wire, the external release mechanism adapted to prevent accidental release of the trigger wires and to allow release of the distal releasing means only after
 2 0 release of the proximal releasing means.

Preferably there is a haemostatic seal around the respective trigger wires in the manipulation section.

The introducer may also include an external sheath extending from external of the patient to cover and compress the graft during insertion of the introducer
 2 5 into a patient and movable longitudinally from outside the patient to expose the graft.

The external sheath may be coaxial with and a sliding fit on the thick walled tube. The external sheath may have a proximal end which is tapered and smoothed to present a low resistance to advancement of the introducer during
 3 0 insertion. The proximal end of the external sheath may also be adapted to have a tight fit on to the proximal attachment device.

Preferably the distal attachment device is of a streamlined shape and is adapted to be advanced to the proximal attachment device whereby to allow smooth retrieval through the released graft and into the external sheath for removal from a patient.

- 5 The introducer according to this invention may be used with a straight tubular self expanding graft or it may be used where the graft is a bifurcated graft.

The introducer according to this invention may be used where the lumen of the patient is an aorta and the graft is adapted to repair an aortic aneurism.

- 10 In an alternative form the invention is said to reside in a method of placing a graft into an internal lumen by means of an insertion assembly the method including the steps of: inserting the insertion assembly including the graft into the internal lumen, withdrawing a sheath from the insertion assembly to expose the graft, releasing the graft from the insertion assembly, replacing the sheath onto the insertion assembly, and retracting the insertion assembly.

- 15 Preferably the graft has a proximal end and a distal end and the insertion assembly includes a proximal attachment device and a distal attachment device adapted to retain the proximal and distal ends of the graft respectively and the step of releasing the graft includes the steps of releasing the proximal end and then the distal end.

- 20 The step of replacing the sheath onto the insertion assembly may include the step of advancing the distal attachment device up to the proximal attachment device and withdrawing the two devices together.

- 25 Between steps (b) and (c) the graft may be manipulated by respective movements longitudinally and rotationally of the proximal attachment device and distal attachment device to correctly position the graft.

Where the graft is a bifurcated graft the step of withdrawing the sheath may include the steps of withdrawing the sheath to a first position in which a side arm of the graft is exposed, insertion of an extension graft into the side arm and then full removal of the sheath from the graft.

- 30 Generally it will be seen that by this invention there is provided an

arrangement by which a graft can be compressed into a thin insertion device and then the insertion device advanced through a vessel such as a femoral artery until the graft is substantially in the position required and then by careful positioning before complete release of the attachment means at each end of the graft, the graft can be placed and released.

The construction of preferred embodiments and the method by which the device may be operated may be made clearer with the aid of the accompanying drawings which show preferred embodiments of the invention and the method by which the device of the various embodiments may be used. For the purpose of clarity the lumen or vasculature into which the graft is to be inserted is not been shown in the drawings.

In the drawings:

Fig 1 shows a first embodiment of an introducer according to this invention fully loaded and ready for introduction into a patient,

Fig 2 shows the embodiment of Fig 1 in the next stage of deployment of the graft,

Fig 3 shows the embodiment of Fig 1 with the release of the proximal end stage of deployment,

Fig 4 shows the release of the distal end stage of deployment,

Fig 5 shows the advancement of the distal attachment device to the proximal attachment device,

Fig 6 shows the withdrawal of the introducer,

Figs 7A - 7C show a part of the introducer adapted for deployment of a bifurcated graft,

Figs 8A - 8E show portions of an alternative embodiment of introducer according to this invention, and

Figs 9A - 9H show a schematic view of the sequence of operations of an

introducer according to the embodiment as shown in Fig 8.

Now looking more closely at the drawings and particularly in the embodiment shown in Figs 1 - 6 it will be seen that the introducer according to this invention comprises generally an external manipulation section 1, a distal attachment region 2 and a proximal attachment region 3.

The proximal attachment region 3 includes a cylindrical sleeve 10 with a long tapered flexible extension 11 extending from its proximal end. The extension 11 has an internal longitudinal aperture 12 to enable it to be advanced along an insertion wire 13 and to enable the supply of medical reagents such as by the use of a contrast agent to allow angiography to be performed during placement and deployment phases of the medical procedure. A thin walled metal tube 15 is fastened to the extension 11 and extends through the complete introducer to the manipulation section and terminates in a connection means 16 for a syringe so that the medical reagent may be introduced into the metal tube and subsequently the extension 11 to emanate through the apertures 14. The thin walled metal tube 15 is flexible so that the introducer can be advanced along a relatively tortuous vessel such as the femoral artery and also to allow manipulation longitudinally and rotationally of the proximal attachment region 3.

The graft 20 is of a self expanding type having resilient stents to enable it to expand after it is released from the introducer. The graft retained within the introducer includes a self expanding zigzag stent 21 extending from its proximal end and in the compressed condition the zigzag stent 21 is retained in the proximal attachment device 10 and fastened in there by means of a trigger wire 22 which extends through an aperture 23 in the side of the proximal attachment device 10 and is received in one of the loops of the zigzag stent. The trigger wire 22 extends along the complete length of the introducer and exits the manipulation region in a side arm 24.

The graft 20 is retained in its compressed condition by means of an external sleeve 30 which is advanced to be received over the proximal attachment device 10 when the device is assembled for insertion.

The external sheath 20 extends distally to external of a patient to the manipulation section and a gripping and sealing means 35.

The distal end of the graft 20 is retained in the distal attachment device 40 which is mounted onto a thick walled plastics tube 41 which extends distally to external of the patient and to the manipulation region 1. The thick walled tube is coaxial with and radially outside the thin walled tube 15 and the sheath 30 is coaxial with and radially outside the thick walled tube 41. The distal end 42 of the graft 20 has a loop 43 through which a distal trigger wire 44 extends. The distal trigger wire extends through an aperture 45 on the distal attachment device into the annular region between the thin walled tube 15 and the thick walled tube 41 like the proximal trigger wire which also extends through the annular space between the thick walled tubing 41 and the thin walled tubing 15 to the manipulation device and out the side arm 24.

Now looking at Fig 2 it will be seen that the external sheath 30 has been withdrawn to just proximal of the distal attachment device 40 so that the graft 20 is now released so that it can expand radially except where the zigzag stent 21 is still retained within the proximal attachment device 10 and where its distal end is retained within the external sheath 30.

By respective movement of the thin walled tubing 15 with respect to the thick walled tubing 41 the graft 20 may now be stretched or rotated or compressed to accurately fit in the desired place within the body lumen. X-ray opaque markers (not shown) may be placed at known places along the graft to assist with placement of the graft.

As shown in Fig 3 the external sheath has been withdrawn to distal of the distal attachment device 40 to allow the distal end of the attachment device to expand. Also the proximal trigger wire 22 has been withdrawn and the thin walled tubing 15 has been pushed in a proximal direction to move the proximal attachment means 10 forward thereby releasing the zigzag stent 21 at the proximal end of the graft from the proximal attachment means. At this stage the hooks 26 on the zigzag stent 21 grip into the walls of the lumen to hold the graft therein. From this stage the proximal end of the graft cannot be moved again. The distal end of the graft 42 is still retained by the distal attachment means 40.

In Fig 4 the distal end 42 of the draft has been released by removal of the distal trigger wire 44. The graft is now free to expand to the walls of the vessel and the introducer is ready to be removed.

The first stage of removal is shown in Fig 5 where the distal attachment device 40 is advanced to be received in the proximal attachment device 10 and then the proximal attachment device 10 including the tapered flexible extension 11 and the distal attachment device 40 are removed together as shown in Fig 6.

- 5 In this embodiment the external sleeve 30 is also removed with the proximal attachment device 10, the tapered flexible extension 11 and the distal attachment device 40 although these could be removed separately and then the external sleeve 30 removed later. This may have some advantage if further surgical procedures are necessary as a clear way is provided to
10 advance other surgical equipment.

Fig 7 shows the use of the introducer according to this invention with a self expanding bifurcated graft

- In Fig 7A the section of the introducer including the proximal attachment device and the distal attachment device of the introducer with a bifurcated
15 graft is shown. The bifurcated graft 50 is retained within the external sheath 51 between the proximal attachment device 52 and the distal attachment device 53 with respective fixings to the proximal attachment device 52 and the distal attachment device 53 of the same form as shown in Figs 1 to 7. The zigzag stents 57 are retained within the proximal attachment device 52.

- 20 After the proximal trigger wire 61 has been released and the proximal attachment device 52 advanced the proximal end of 56 of the graft 50 is released and the zigzag stents 57 are free to expand. At this stage the distal end 58 of the graft 50 is still retained in the distal attachment means 53.

- At this stage an extension piece 59 can be inserted into the side arm 60 by a
25 separate introducer from the other femoral artery as shown in Fig 7C. The release of the distal attachment device and the withdrawal of the introducer can then proceed in the same manner as discussed with respect to Figs 1 to 7.

- An alternative embodiment of introducer according to this invention is shown in Figs 8A - 8E which show the various portions of the introducer along its
30 length.

Commencing from the proximal end as shown in Fig 8A the alternative embodiment includes a tapered flexible extension 70 extending from a

proximal attachment device 71. The tapered flexible extension 70 includes side holes 72 and a longitudinal aperture 73. A trigger wire 74 extends into an aperture 75 within the proximal attachment device 71 to pass through a loop 79 of a zigzag stent 76 extending from the proximal end of a self expanding graft 77. A thin walled metal tube 78 is fastened to the proximal attachment device and the tapered flexible extension and extends in a distal direction from the proximal attachment device to external of the patient in use.

The distal attachment device 80 includes a slot 81 as more particularly can be seen in the enlargement of the distal attachment device into which a loop 82 of the self expanding graft can be received such that a distal trigger wire 83 can be passed through the loop to retain the loop and hence the distal end of the graft. The end 84 of the trigger wire 83 is conveniently clipped back into the graft to keep it out of the way. The distal attachment device 80 is fastened to a thick walled tubing 86 which extends to external of a patient in use. There is an annular space 87 between the thick walled tubing 86 and the coaxial thin walled tube 78 and the distal and proximal trigger wires pass through this annular space to external of the patient.

An external sheath 88 is concentric with the thick walled tubing 86 and a sliding fit thereon. The proximal end 89 of the external sheath is polished and smoothed so that it presents a smooth surface as it is passed into the lumen.

At the insertion stage the external sheath 88 is advanced over the compressed self explaining graft 77 so that it is received onto the proximal attachment device 71.

Fig 8C shows part of the manipulation section which in use is external of the patient. The external sheath 88 terminates in a gripping and sealing assembly 90 which includes a haemostatic seal 91 to seal the external sheath to the thick walled tubing 86. A side arm 92 is provided to enable introduction of medical fluids to provide a positive pressure within the external sheath to prevent blood travelling down between the external sheath and the thick walled tubing 78.

Figure 8D continues the external manipulation section of the introducer. The thick walled tubing 86 terminates in a mounting body 95. A proximal

attachment release mechanism 96 and a distal attachment release mechanism 97 is provided on the mounting body 95. The distal attachment trigger wire 83 extends into the distal attachment release mechanism 97 and the proximal trigger wire 74 extends into the proximal attachment release mechanism 96. Thumb screws 98 enable the respective attachment release mechanisms to be fastened to the mounting 95 to prevent their premature release.

When the respective attachment release mechanisms are to be released the thumb screw 98 are loosened. First of all the proximal attachment release mechanism 96 can be moved away from the distal attachment release mechanism 97 so that the proximal trigger wire 74 is released first. By the construction and placement of the proximal attachment release mechanism 96 and the distal attachment release mechanism 97 and their arrangement on the mounting body 95 it will be noted that the distal attachment release mechanism 97 cannot be moved until the proximal attachment release mechanism 96 has been moved.

A haemostatic seal 99 is provided where the respective attachment wires pass out of the mounting 95.

The mounting 95 terminates in a locking device generally shown as 100 by which the mounting 95 can be locked to the thin walled tubing 78 or released so that the coaxial thin and thick walled tubes can be moved separately or together. A haemostatic seal 101 is provided between the thin walled tubing and the mounting 95. A pin vice arrangement 102 is provided to enable locking of the locking device onto the thin walled tubing 78.

The thin wall tubing 78 terminates in a syringe fitting 104 so that a syringe may be mounted onto the end of the tubing to enable supply of medical reagents such as contrast reagents for x-raying to be passed through the thin walled tubing 78 to the side holes 72 in the tapered flexible extension 70 as shown in Fig 8A.

The sequence of operation for the insertion and release of the graft as detailed in Figs 8A - 8E is shown in Figs 9A - 9H.

The full assembly is shown diagrammatically in Fig 9A with the graft contained

within the external sheath 88 and fastened at the proximal end to the proximal attachment device 71 and at its distal end to the distal attachment device 80. The tapered extension 70 extends proximally from the proximal attachment device 71 and the thick walled tubing 86 extends distally from the distal attachment device 80.

The first stage in the release procedure is shown in Fig 9B with the external sheath 88 withdrawn to be distal of the distal attachment device 80 so that the graft 77 can expand except where the proximal end of the graft is still retained within the proximal attachment device 71 and the distal end is retained to the distal attachment device 80.

As shown in Fig 9C the locking mechanism 100 is released and moved towards the syringe fitting 104 so that the thin walled tubing 78 and hence the proximal attachment device 71 and the tapered flexible extension 70 can be advanced.

At the same time the proximal attachment release mechanism 96 is removed which in turn removes the proximal trigger wire 74 to release the grip on the zigzag stent at the proximal end of the graft. When the locking mechanism and thin walled tube 78 is moved forward then the proximal attachment device is advanced allowing the proximal end of the graft to expand as shown in Fig 9D.

As shown in Fig 9E the distal attachment release mechanism 97 has been removed which removes the distal trigger wire 83 which enables the distal attachment device to be withdrawn thereby freeing the distal end of the graft.

At this stage the graft is completely deployed and the introducer can now be withdrawn.

The first stage of withdrawal of the introducer is shown in Fig 9F.

At this stage the thick walled tubing 86 incorporating the distal attachment device 80 is advanced to dock with the proximal attachment device 71 and then the locking mechanism 100 is released and moved forward to lock with the mounting body 95 to lock the coaxial thin walled tube 78 and thick walled tube 86 together as shown in Fig 9G.

The proximal and distal attachment devices are then withdrawn together through the sheath 88 and then the sheath 88 is withdrawn from the patient.

5 It will be seen that by this invention a graft can be inserted into a patient with a clear series of steps to release the graft within the patient and to retrieve the introducer.

Throughout this specification unless the context requires otherwise, the words 'comprise' and 'include' and variations such as 'comprising' and 'including' will be understood to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

10 Throughout this specification various indications have been given as to the scope of this invention but the invention is not limited to any one of these but may reside in two or more of these combined together. The examples are given for illustration only and not for limitation.

1. An introducer adapted for the introduction of a self expanding
 15 endovascular graft into a lumen of a patient, the graft having a proximal end and a distal end, the introducer comprising,
 a. a proximal attachment device adapted to be attached to the proximal end of the graft,
 b. distal attachment device adapted to be attached to the distal end
 20 of the graft,
 c. each of the proximal and distal attachment devices attaching to the graft in such a manner that the graft can be held in tension therebetween and that each end of the graft can individually be moved in proximal and distal directions and be rotated, and
 25 d. proximal releasing means associated with the proximal attachment device and distal releasing means associated with the distal attachment device to enable selective releasing of the proximal and distal ends of the graft.

2. An introducer as in claim 1 wherein the proximal attachment means
 30 has a long flexible extension on its proximal end to facilitate insertion of the introducer into a body lumen and its advancement along the lumen.

3. An introducer as in claim 2 wherein the proximal attachment device is mounted on a flexible thin walled tube which extends in a distal diversion

for the proximal attachment device to an external manipulation section of the introducer which is adapted to remain external of the patient.

4. An introducer as in claim 3 wherein the thin wall metal tube includes fluid connection means external of the patient to enable the introduction of a medical reagent therethrough.
5. An introducer as in claim 4 wherein the long flexible extension includes a hollow tube therethrough in fluid communication with the thin wall metal tube and a plurality of side holes to enable dispersion of the medical reagent proximal of the graft.
6. An introducer as in claim 3 wherein the distal attachment device is mounted on a flexible thick walled tubing and coaxial on the thin walled tube and extending in a distal direction to the external manipulation section and mounted such that the respective tubes can be moved together or independently.
7. An introducer as in claim 6 including a haemostatic seal between the thin walled tube and the thick walled tube in the manipulation section.
8. An introducer as in claim 7 including means to introduce a medical reagent into an annular space defined between the thin walled tube and the thick walled tube.
9. An introducer as in claim 1 including a proximal trigger wire extending from the proximally attachment device to the manipulation section, the proximal trigger wire being adapted to activate the proximal releasing means.
10. An introducer as in claim 1 including a distal trigger wire extending from the distal attachment device to the manipulation section, the distal trigger wire being adapted to activate the distal releasing means.
11. An introducer as in claim 1 including an external release mechanism for each of the proximal trigger wire and distal trigger wire, the external release mechanism adapted to prevent accidental release of the trigger wires and to allow release of the distal releasing means only after release of the

proximal releasing means.

12. An introducer as in claim 11 including a haemostatic seal around the respective trigger wires in the manipulation section.

5 13. An introducer as in claim 1 including an external sheath extending from external of the patient to cover and compress the graft during insertion of the introducer into a patient and movable longitudinally from outside the patient to expose the graft.

14. An introducer as in claim 13 wherein the external sheath is coaxial with and a sliding fit on the thick walled tube.

10 15. An introducer as in claim 14 wherein the external sheath has a proximal end which is tapered and smoothed to present a low resistance to advancement of the introducer during insertion.

16. An introducer as in claim 13 wherein the proximal end of the external sheath is adapted to have a tight fit on to the proximal attachment device.

15 17. An introducer as in claim 1 wherein the distal attachment device is of a streamlined shape and is adapted to be advanced to the proximal attachment device whereby to allow smooth retrieval through the released graft and into the external sheath for removal from a patient.

18. An introducer as in claim 1 wherein the graft is a bifurcated graft.

20 19. An introducer as in any one previous claim wherein the lumen of the patient is an aorta and the graft is adapted to repair an aortic aneurism.

20. A method of placing a graft into an internal lumen by means of an insertion assembly the method including the steps of:

- 25
- a. inserting the insertion assembly including the graft into the internal lumen,
 - b. withdrawing a sheath from the insertion assembly to expose the graft,
 - c. releasing the graft from the insertion assembly,
 - d. replacing the sheath onto the insertion assembly, and

e. retracting the insertion assembly.

21. A method as in claim 20 wherein the graft has a proximal end and a distal end and the insertion assembly includes a proximal attachment device and a distal attachment device adapted to retain the proximal and distal ends of the graft respectively and the step of releasing the graft includes the steps of releasing the proximal end and then the distal end.

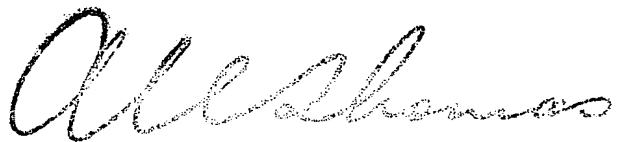
22. A method as in claim 21 wherein the step of replacing the sheath onto the insertion assembly includes the step of advancing the distal attachment device up to the proximal attachment device and withdrawing the two devices together.

23. A method as in claim 21 wherein between steps (b) and (c) the graft is manipulated by respective movements of the proximal attachment device and distal attachment device to correctly position the graft.

24. A method as in claim 20 wherein the graft is a bifurcated graft and the step of withdrawing the sheath includes the steps of withdrawing the sheath to a first position in which a side arm of the graft is exposed, insertion of an extension graft into the side arm and then full removal of the sheath from the graft.

Dated this 26th day of May 1997

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By their Patent Attorneys,
COLLISON & CO.



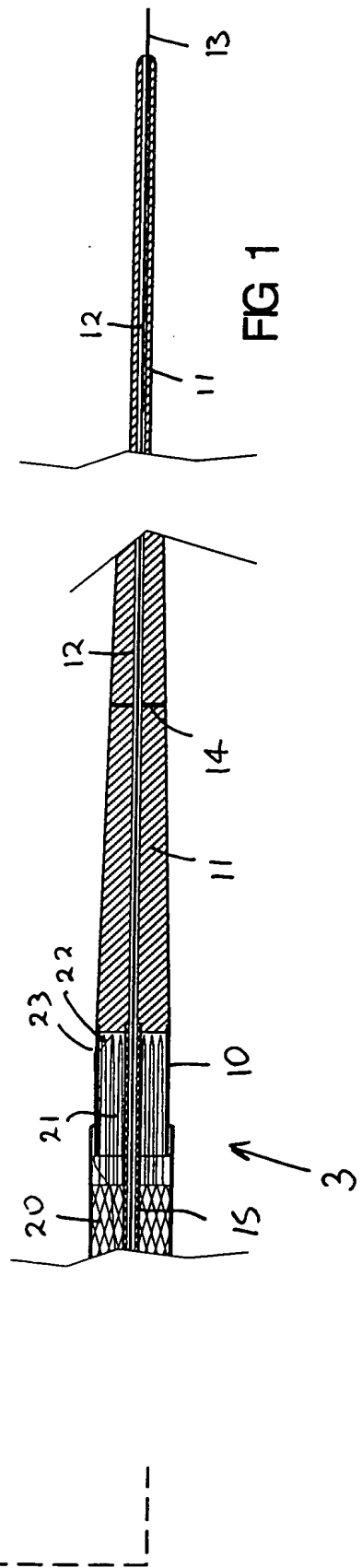
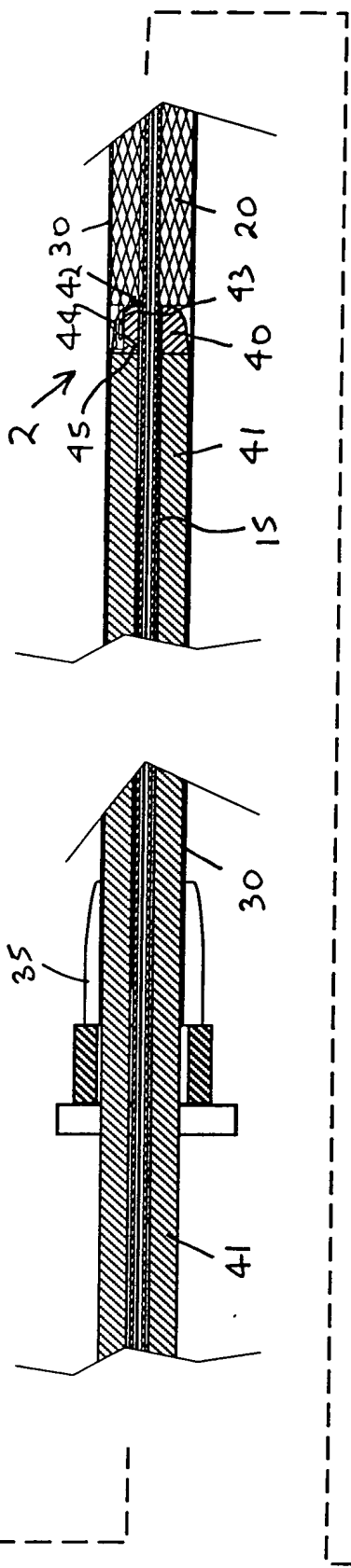
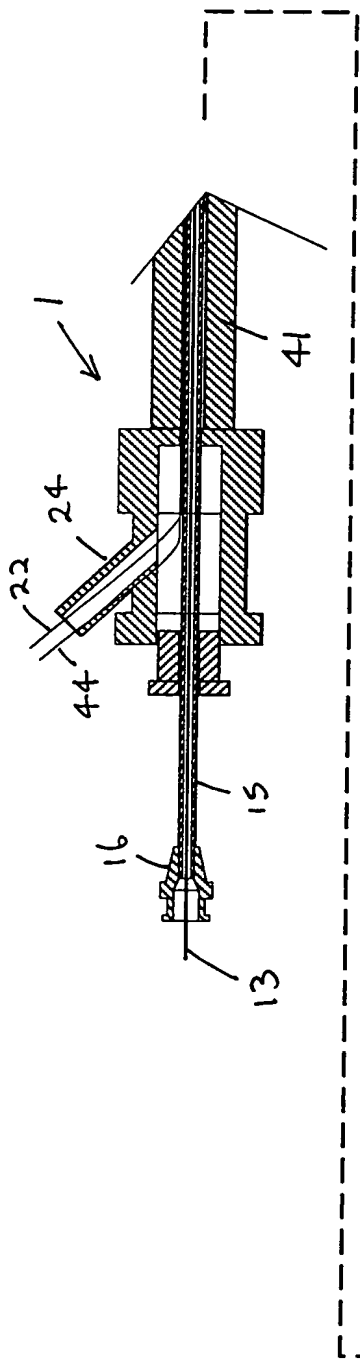


FIG 1

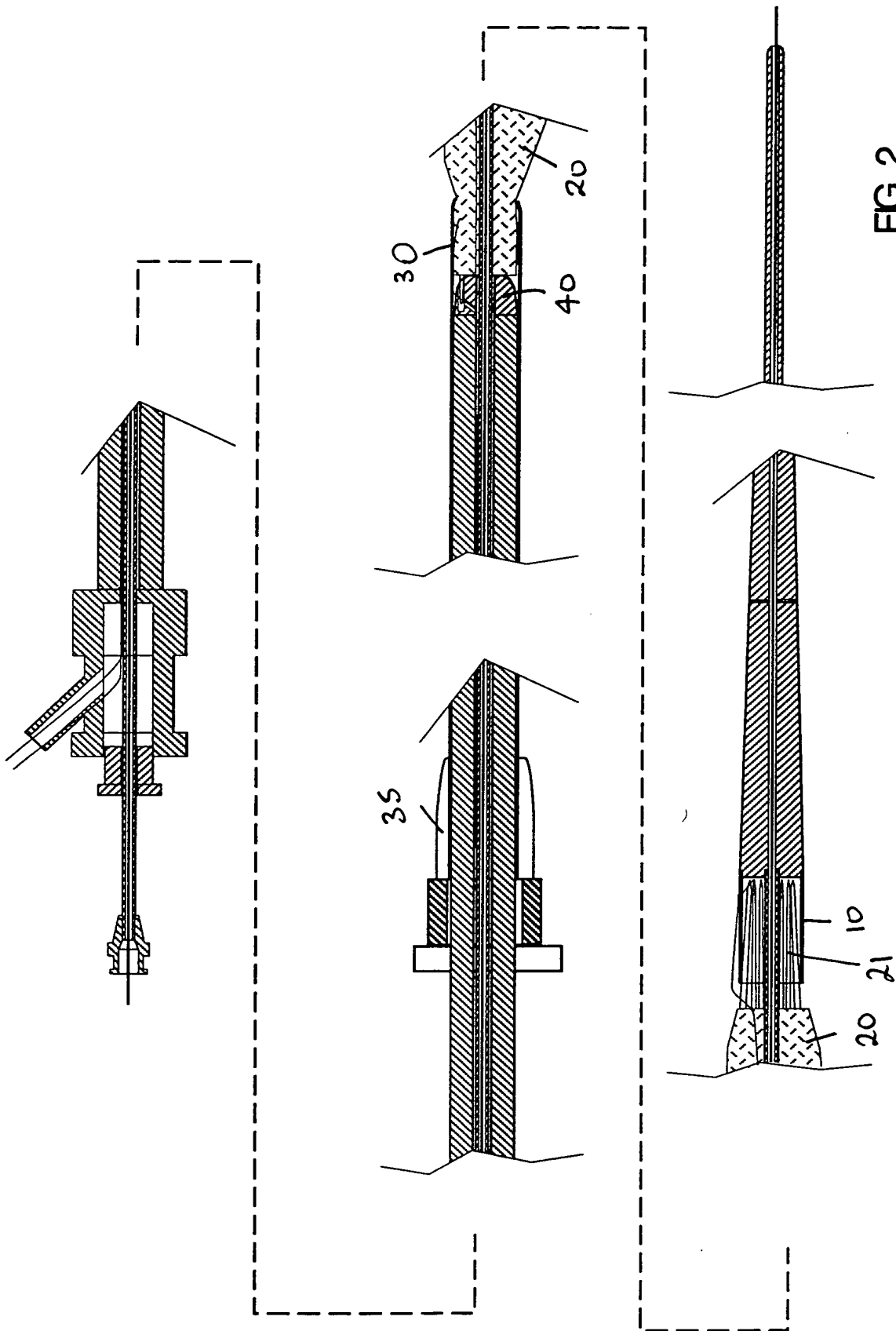


FIG 2

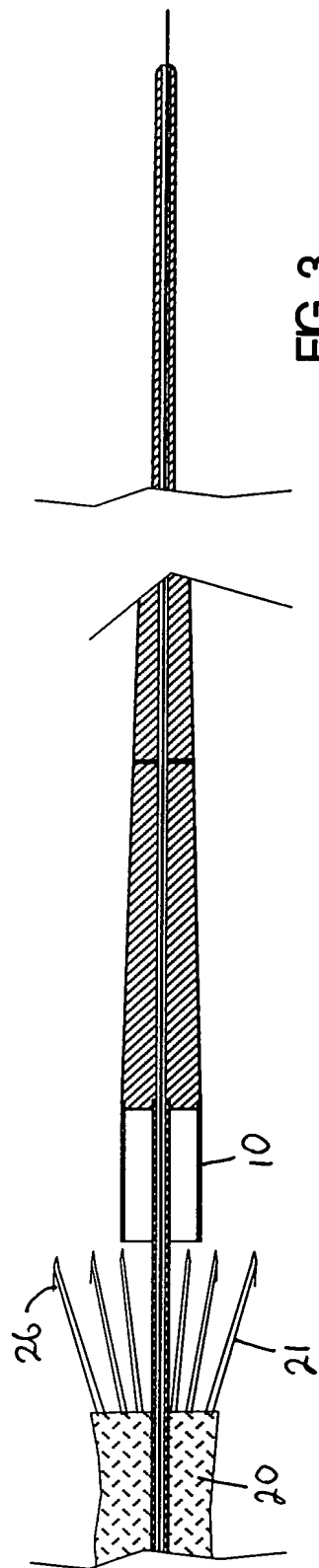
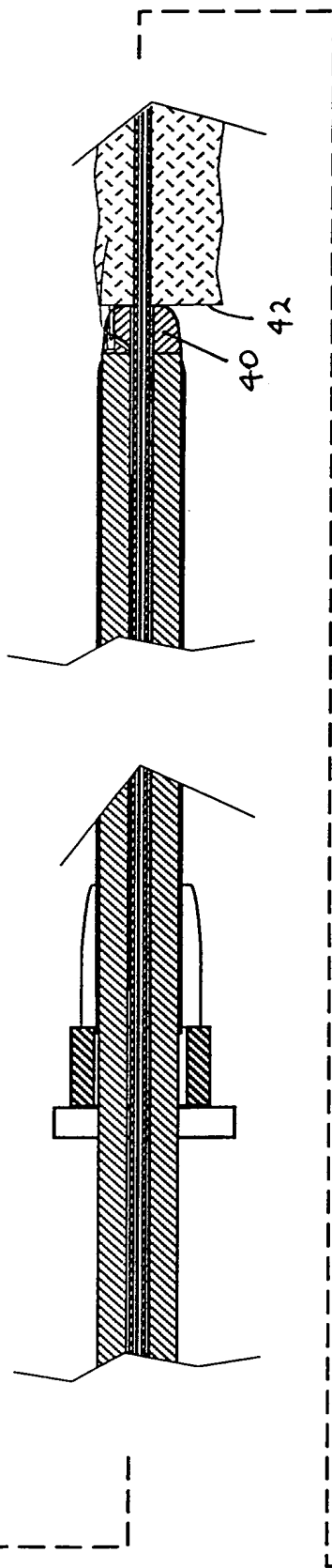
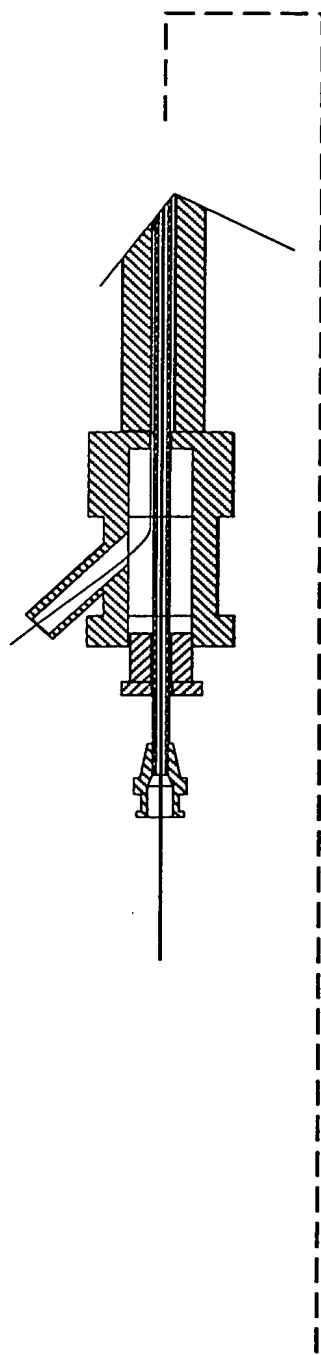


FIG 3

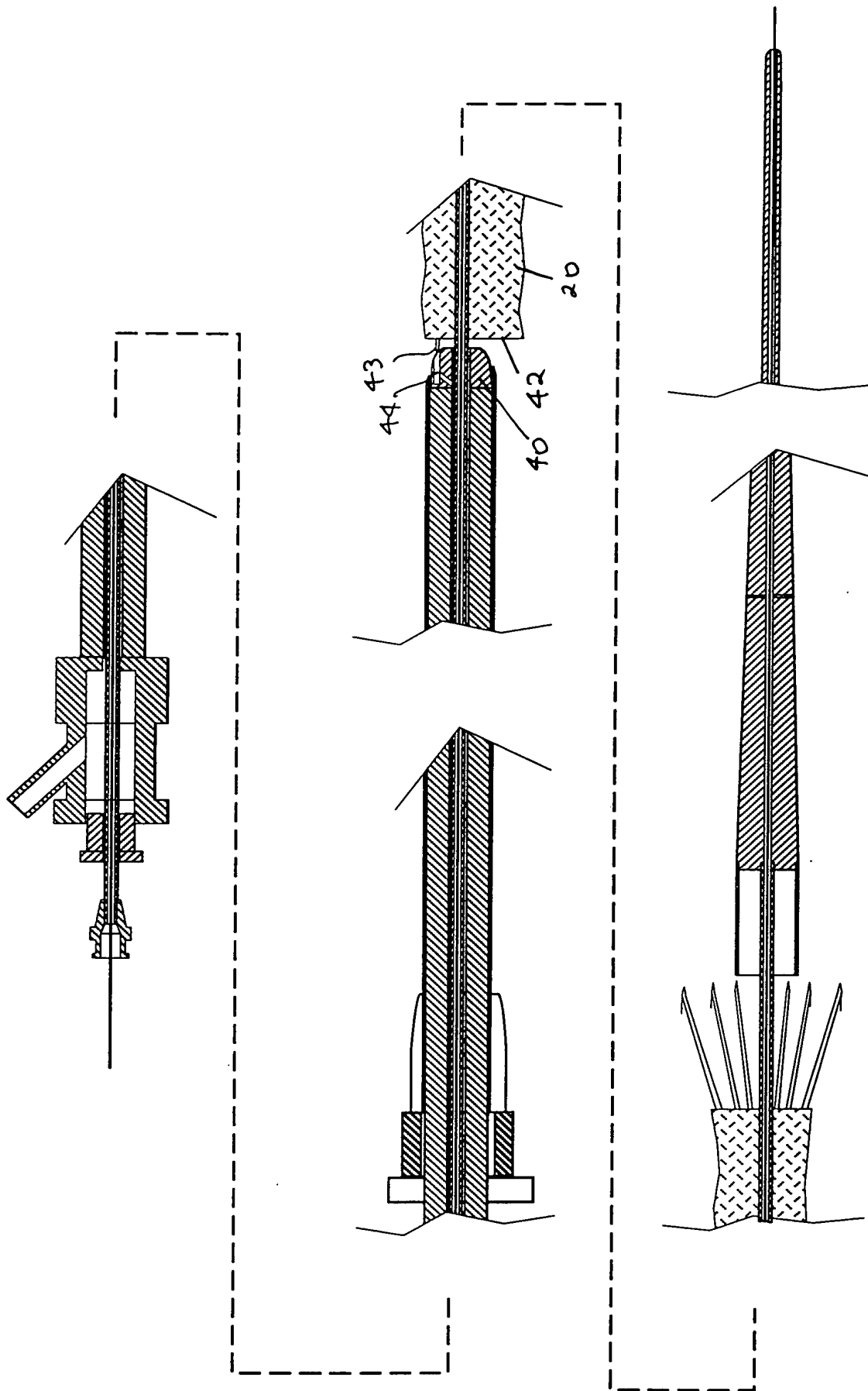


FIG 4

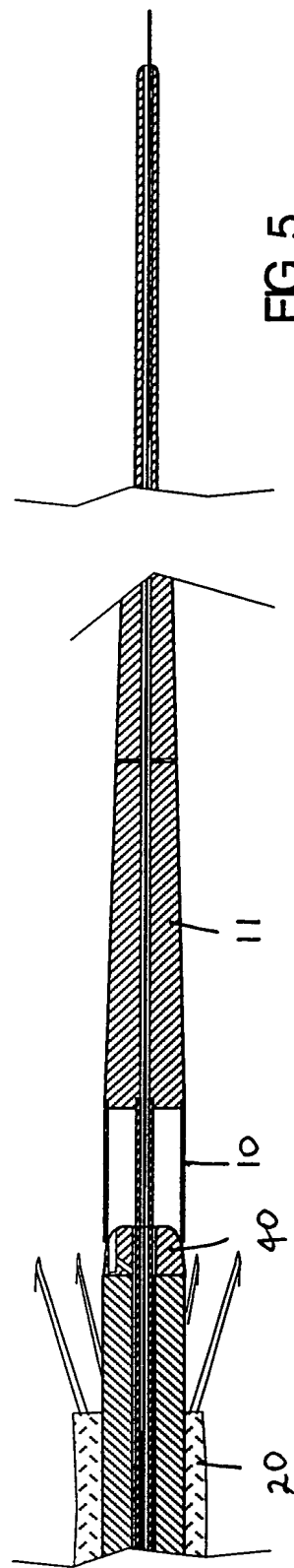
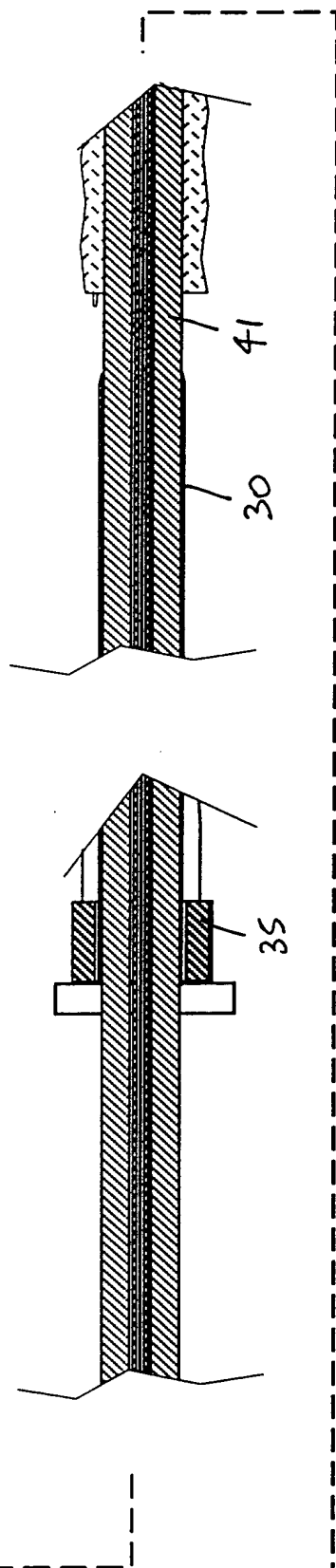
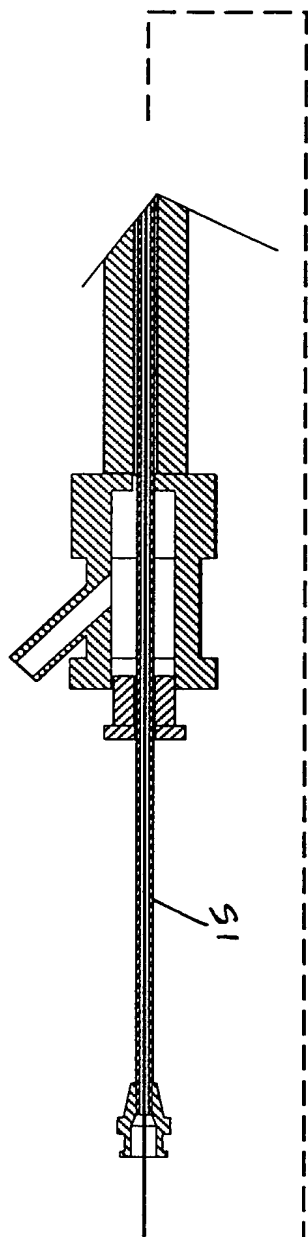


FIG 5

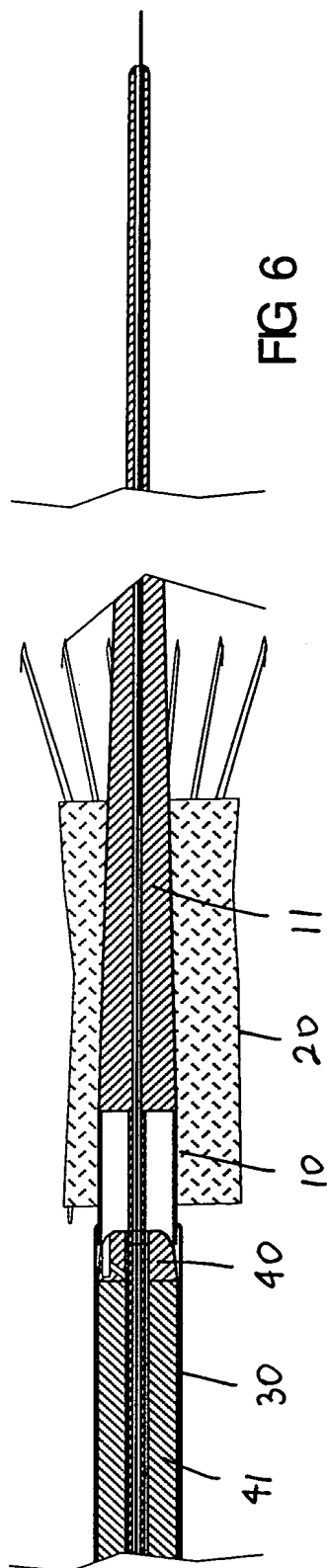
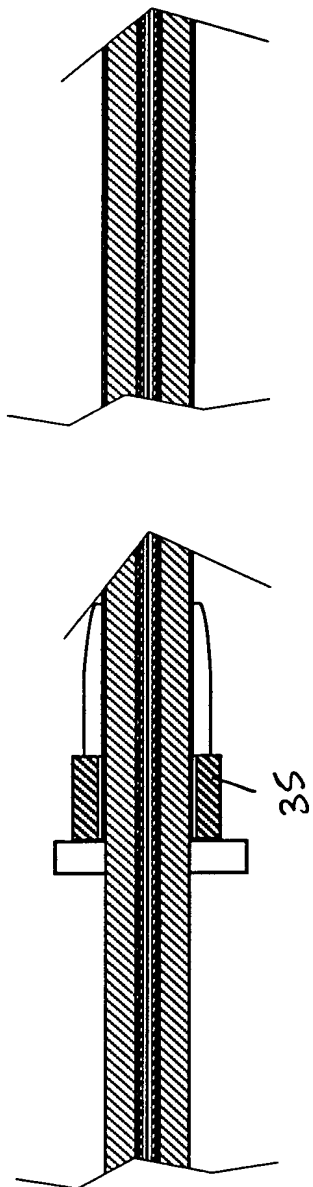
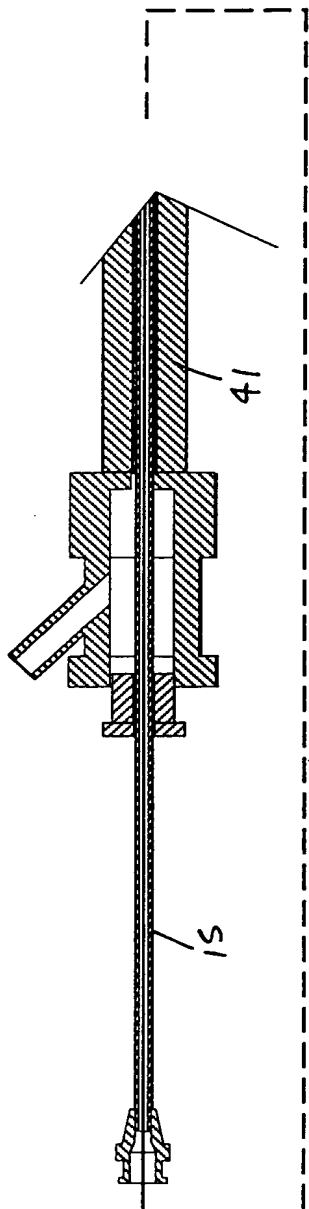


FIG 6

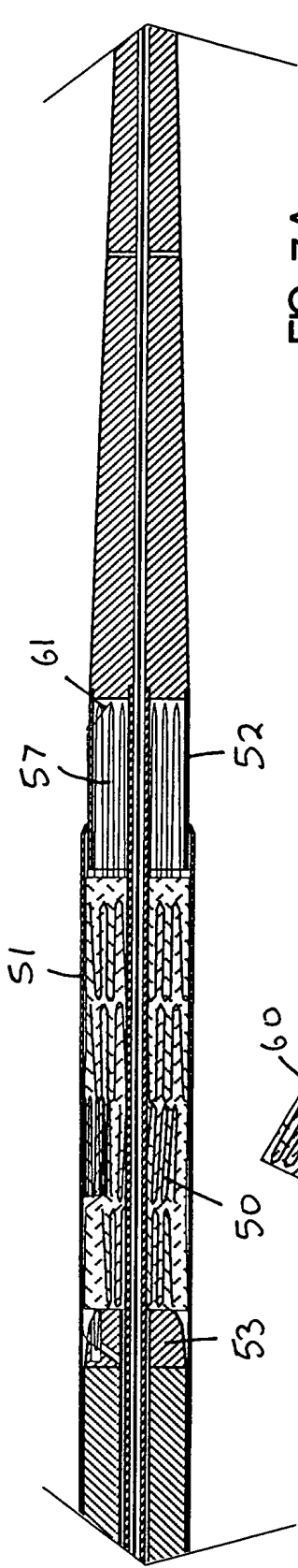


FIG 7A

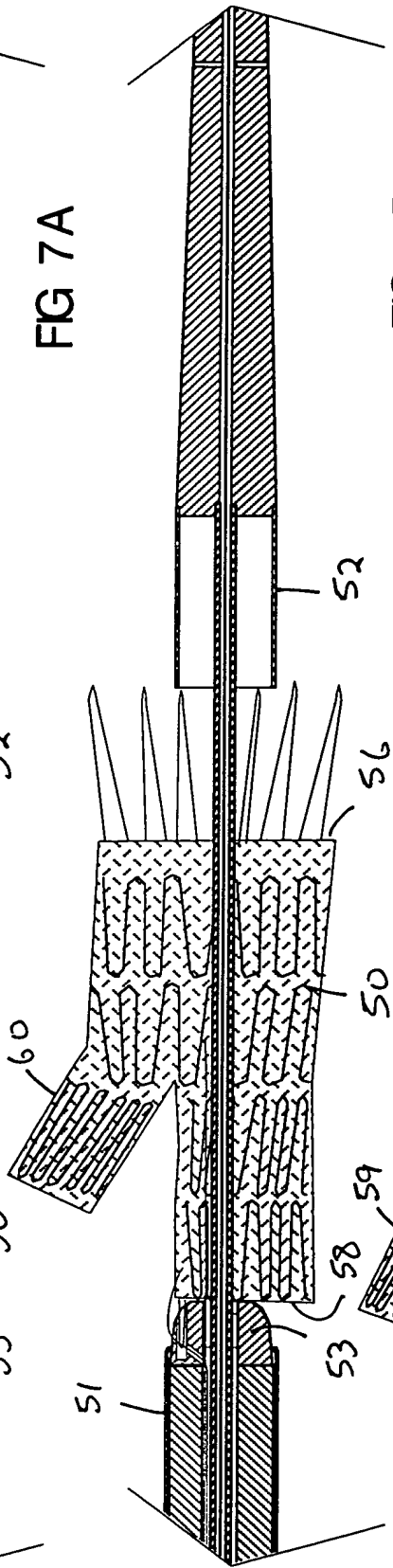


FIG 7B

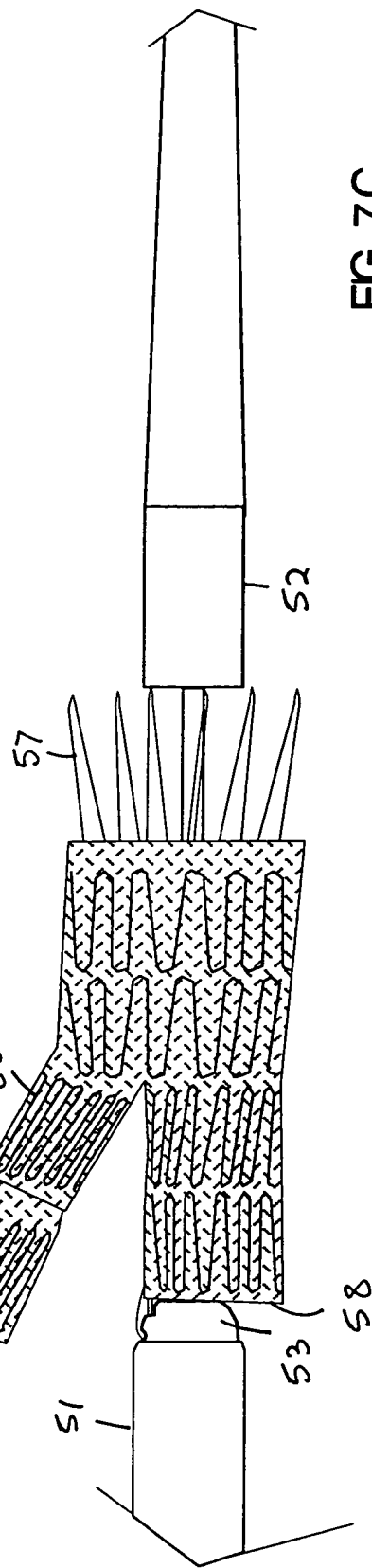
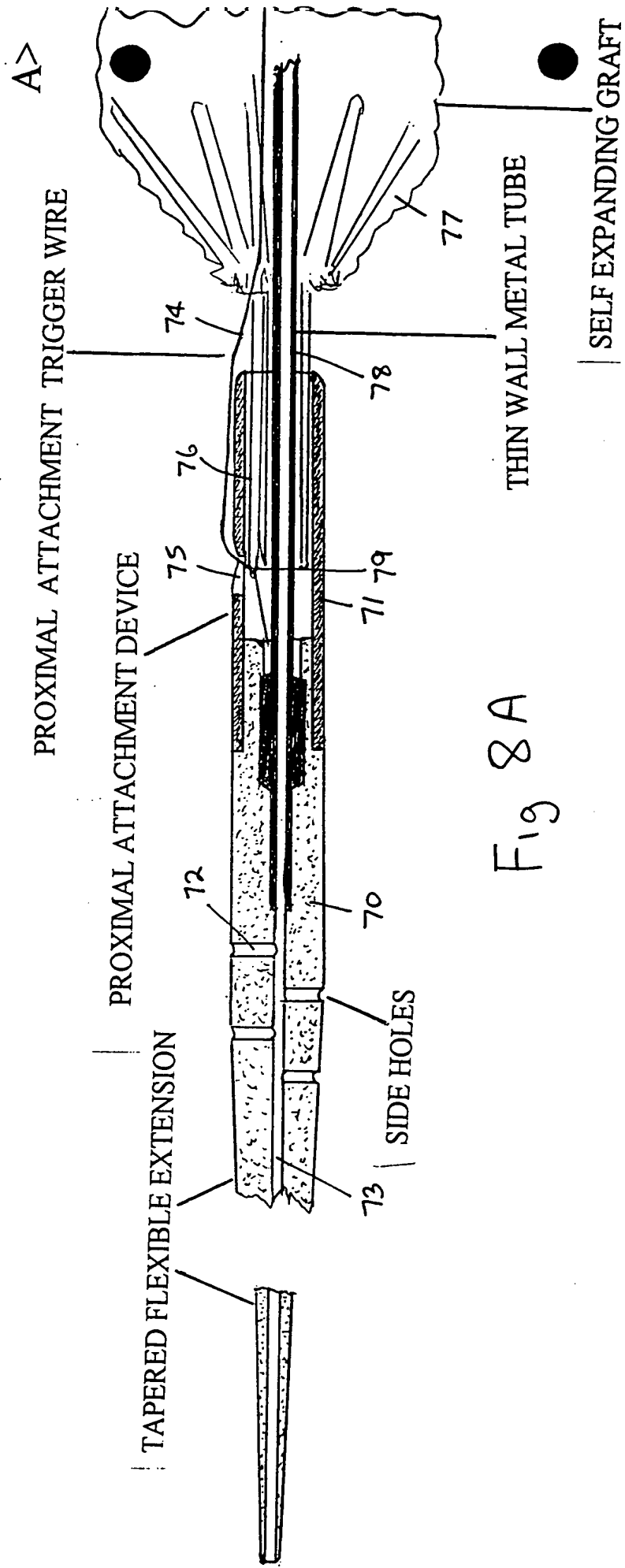
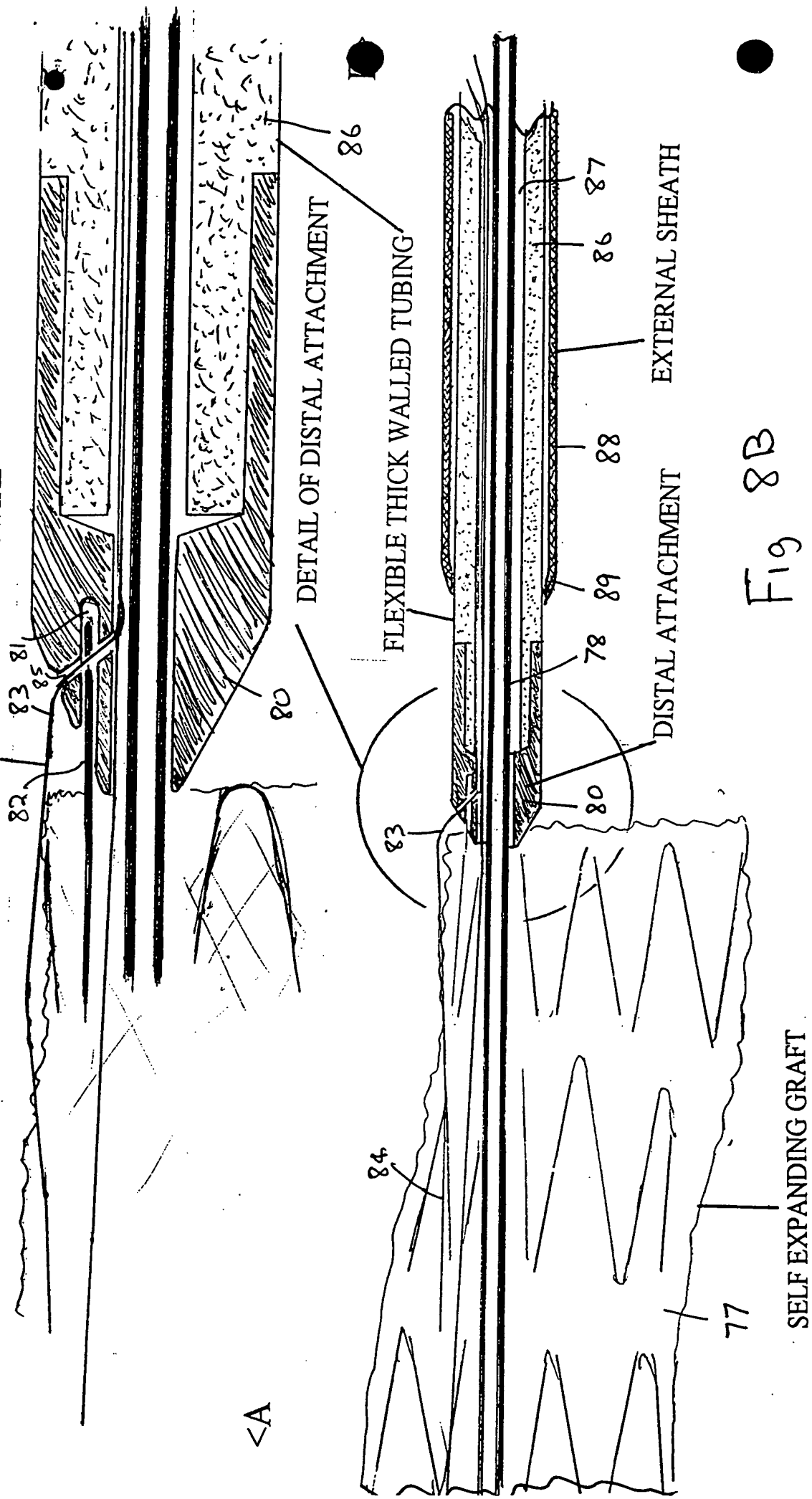


FIG 7C



DISTAL ATTACHMENT TRIGGER WIRE



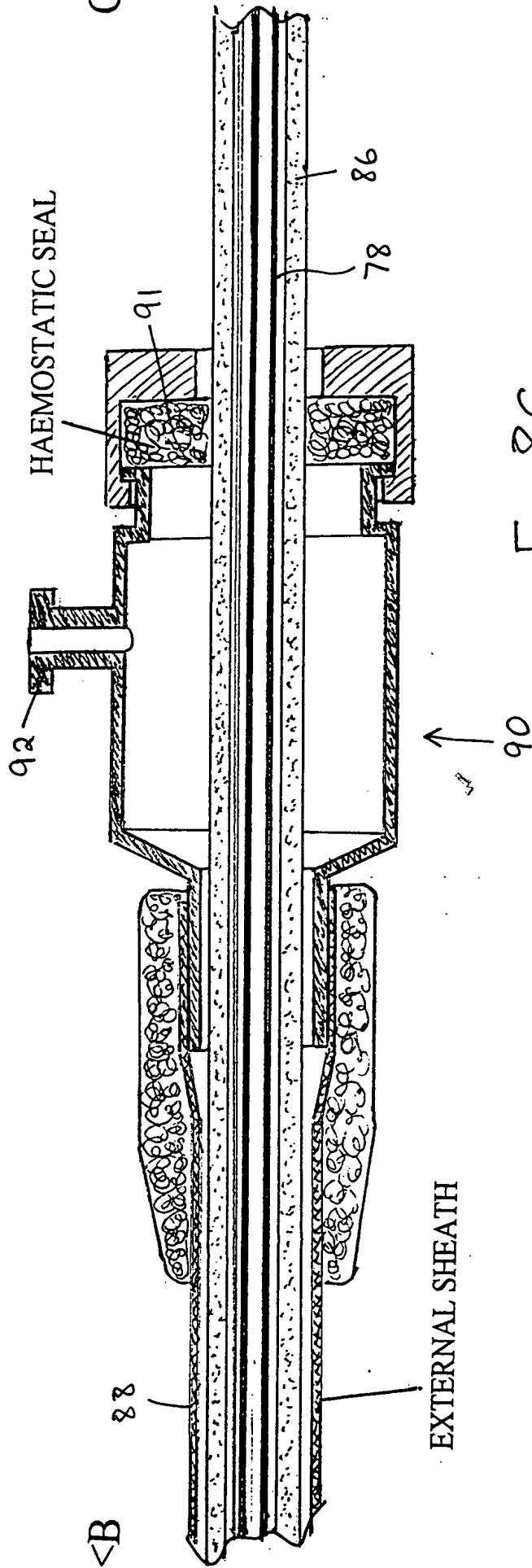


Fig 8C

PROXIMAL ATTACHMENT RELEASE MECHANISM

DISTAL ATTACHMENT RELEASE MECHANISM

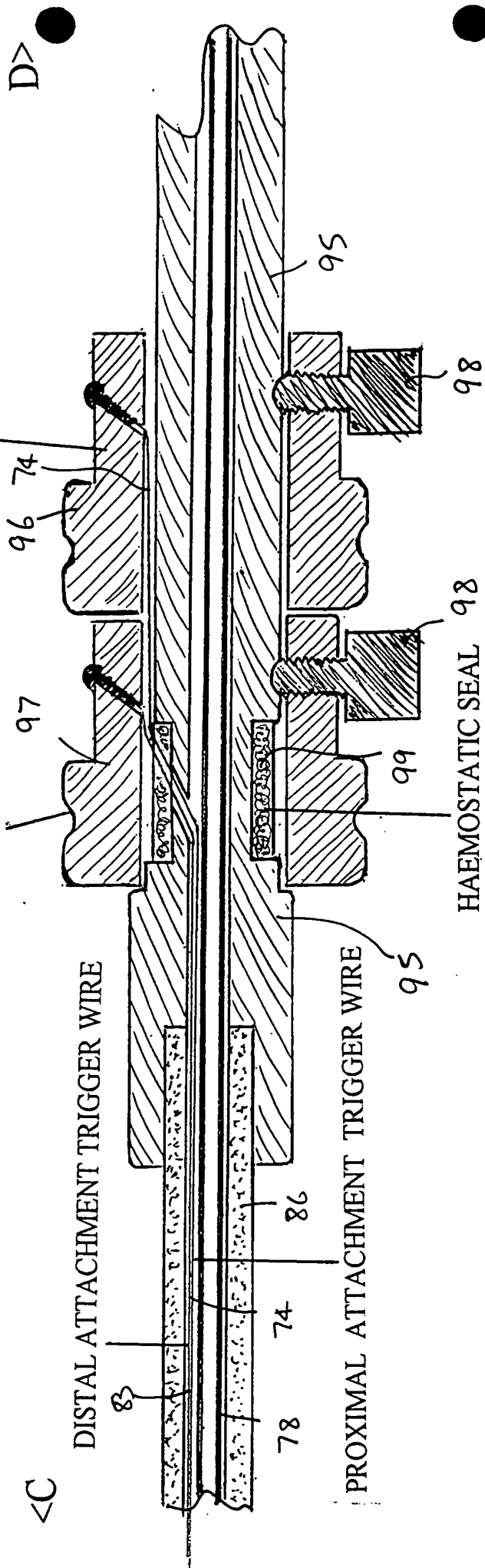


Fig 8D

<D

DEVICE FOR LOCKING CO-AXIAL TUBES TOGETHER

HAEMOSTATIC SEAL

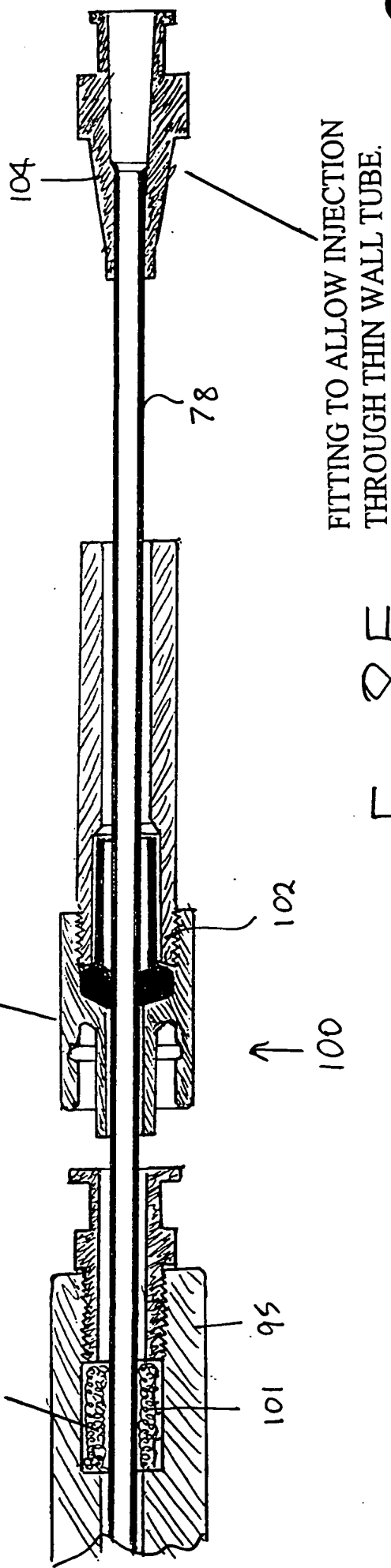
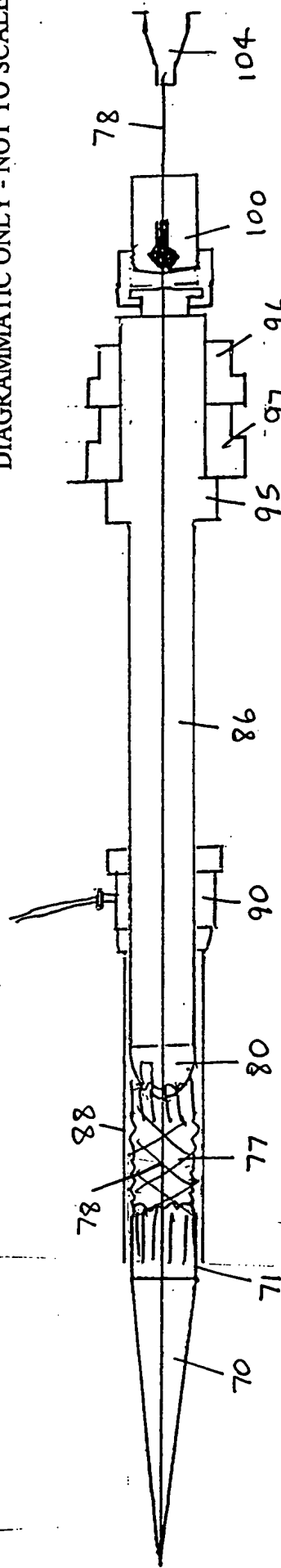


Fig 8E

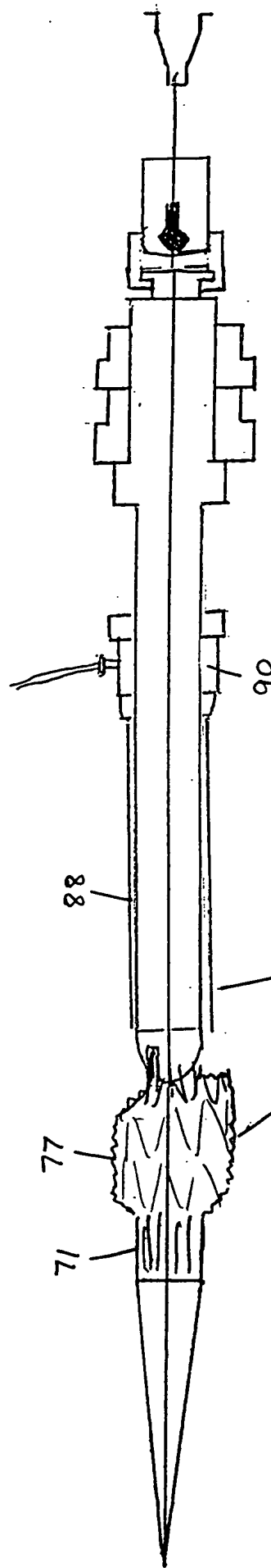
SEQUENCE OF OPERATIONS FOR THE HLB ENDOGRAFT "ONE SHOT" INTRODUCER

DIAGRAMMATIC ONLY - NOT TO SCALE



GRAFT / STENT AT INSERTION CONTAINED IN EXTERNAL SHEATH

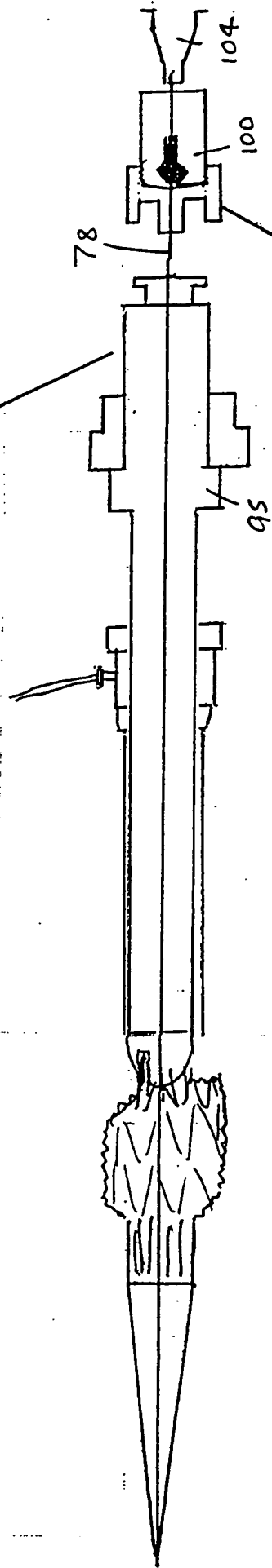
Fig 9A



EXTERNAL SHEATH WITHDRAWN
ALLOWING
MIDDLE AND DISTAL GRAFT TO EXPAND

Fig 9B

PROXIMAL ATTACHMENT TRIGGER WIRE WITHDRAWN



CO-AXIAL TUBING LOCK RELEASED
AND
RE-LOCKED ON THIN WALLED METAL TUBE

Fig 9C

PROXIMAL ATTACHMENT DEVICE ADVANCED
ALLOWING
PROXIMAL GRAFT TO EXPAND

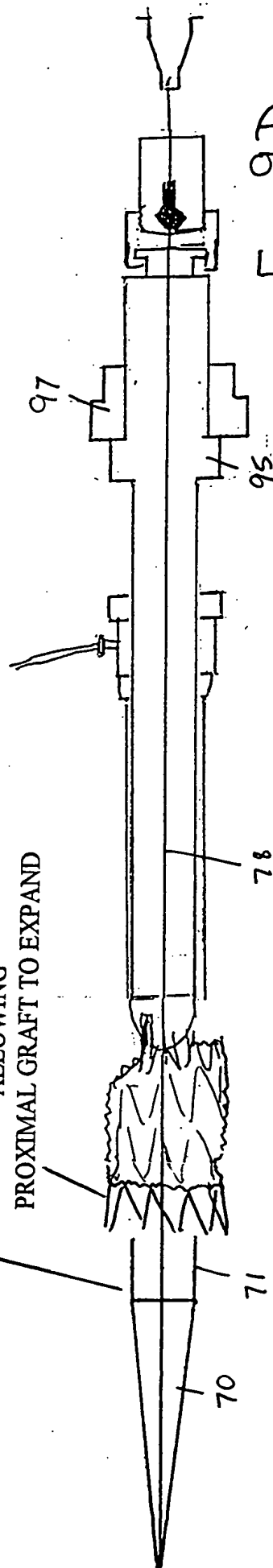


Fig 9D

DISTAL ATTACHMENT DEVICE WITHDRAWN

FREEING
DISTAL GRAFT

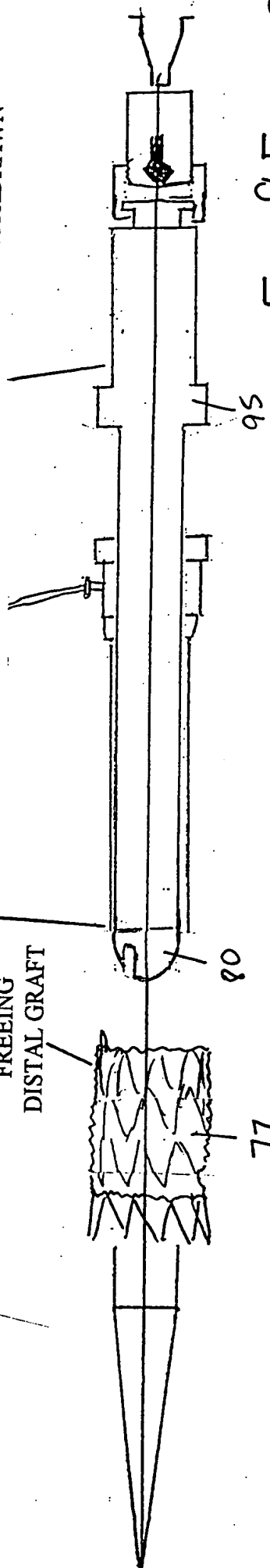


Fig 9E

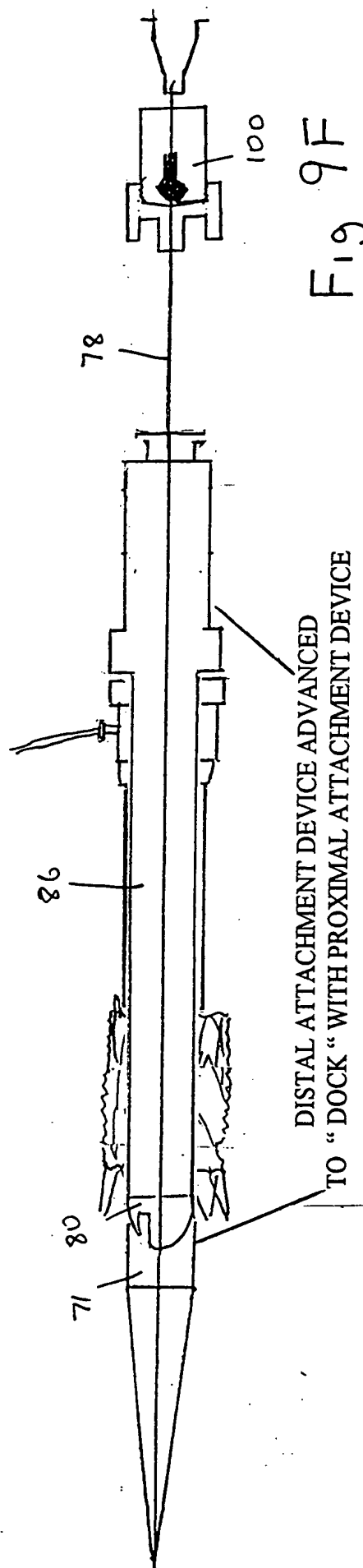


Fig 9F

